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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,574	07/16/2002	Wolf Bertling	10848-018001	7496

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,574	BERTLING, WOLF	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/24/02, 04/01/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The Preliminary Amendment filed July 16, 2002 is acknowledged and has been entered. Claims 15-23 have been canceled and claims 24 and 25 have been added. Thus, claims 1-14, 24 and 25 are currently pending.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

1. The disclosure is objected to because of the following informalities: The disclosure fails to provide the following headings: BRIEF SUMMARY OF THE INVENTION, BRIEF DESCRIPTION OF THE DRAWINGS, and DETAILED DESCRIPTION OF THE INVENTION.

2. The disclosure is objected to because of the following informalities. On page 3, lines 29-31. The specification discloses "This object is achieved by the features of claims 1 and 11. Expedient developments of the invention are evident from the features of claims 2 to 10 and 12-20. This is objected to because it is unclear what is encompassed by referring to the claims. Further, the claims are subject to being amended such as done by applicant in the preliminary amendment filed July 16, 2002. For example, claims 15-20 have been cancelled. It is recommended to remove the reference to claims from the disclosure.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plasma, blood, saliva and urine samples,

does not reasonably provide enablement for any and all body fluid samples. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re W*ands USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to a method for indirectly determining blood clotting status comprising providing a sample of body fluid which contains a protein which can be modified by a vitamin K-dependent gamma-carboxylase. The specification on page 7, lines 1-4 disclose the body fluid may expediently be plasma, blood, saliva, urine or the like and that all body fluid in which the modifiable protein is present in a content which makes measurement possible are suitable in principle. However, the specification does not disclose fluids such as tissue fluids or serum. Serum is known in the art to be the watery portion of the blood after coagulation; a fluid found when clotted blood is left standing long enough for the clot to shrink (see definition of serum in Taber's Cyclopedic Medical Dictionary, attached hereto). Brown

(Hematology, Principles and Procedures, Sixth Edition, page 213) teaches that in coagulation procedures tissue fluids lead to incorrect results and that the presence of a clot irrespective of how small it is renders the specimen unacceptable for coagulation testing. Thus one of ordinary skill in the art would have a low predictability in the art. The working examples are limited to plasma samples. At best, the accurate detection of the blood clotting status can be determined only in samples of plasma, blood, saliva or urine. Such is not seen as sufficient to support the breath of the claims and one skilled in the art cannot practice the invention without undue experimentation, because in order to select an appropriate sample and expect determining the blood clotting status, one skilled in the art would have to have a high level of predictability, in order to successfully select an appropriate sample without undue experimentation.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-14, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1 the recitation "blood clotting status" is vague and indefinite. It is unclear what the term encompasses. Does applicant intend clotting time or something other than clotting time such as a specific clotting parameter? The specification does not provide a definition of the phrase. The specification on page 9 discloses the blood

clotting status INR. It is recommended to change "blood clotting status" to - -blood clotting status INR (International Normalized Ratio)--.

Claim 4 is vague and indefinite. It is unclear what applicant intends. Does applicant intend that step b) of claim 1 or claim 2 is replaced. Further, Claim 1 from which the depending claims depend requires measuring two concentrations and to replace this step would fail to further limit claim 1, as the scope of claim 1 would be changed. Does applicant intend that claim 1 would additionally comprise the recitation of claim 4? Please clarify.

Claim 4 the recitation " a combined signal correlating therewith" is vague and indefinite. It is unclear what applicant intends or is trying to encompass. Please clarify.

Claim 5, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 6, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 11 "generate a combined signal" is vague and indefinite. It is unclear how a combined signal is generated. Does each antibody comprise a different label which when combined together would generate a different signal or does each antibody comprise the same label which is read and the intensity of each combined? Please clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Furie et al (US 4,769,320).

Furie et al disclose a kit (col 26). Furie et al disclose an antibody specific for a carboxylated protein. Furie et al also disclose an antibody specific for decarboxylated protein (col 12 and col 27). Furie et al disclose that the antibodies can be labeled and placed into a kit (col 26). Furie et al disclose that the protein is prothrombin.

With respect to claim 12, Furie et al disclose that the label can be an enzyme (col 4).

With respect to the recitation "for carrying out the method as claimed in claim 1" this is intended use of the kit and a recitation of intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and since Furie et al disclose the same components as the instantly recited claims, Furie et al reads on the instantly recited claims and is capable of performing the method. Further, since Furie et al disclose the same components as recited in the kit the labeled antibodies of Furie et al would be able to generate a combined signal.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furie et in view of Akhavan-Tafti et al (US 5,843,666).

See above for the teachings of Furie et al.

Furie et al differ from the instant invention in failing to specifically teach the combined signal is a combined color.

Akhavan-Tafti e al disclose a first antibody labeled with alkaline phosphatase and a second antibody labeled with horseradish peroxidase. Akhavan-Tafti et al disclose that the combined action of the of both the hydrolytic enzyme and the peroxidase enzyme,operatesto produce a detectable chemiluminescent signal (color). Akhavan-Tafti et al teaches that the use of these labels provides for methods to detect and

quantitate with improved specificity various biological molecules including antigens and antibodies by the technique of immunoassay.

It would have been obvious to one of ordinary skill at the time the invention was made to incorporate labels as taught by Akhavan-Tafti et al with the antibodies and kit of Furie et al because Furie et al specifically teaches that the immunoassay can be enzyme-linked assays and because Akhavan-Tafti et al teaches that the use of these labels provides for methods to detect and quantitate with improved specificity various biological molecules including antigens and antibodies by the technique of immunoassay.

Conclusion

12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

De Nora et al (US 6,503,724) disclose method for determining blood coagulation status of F1+2, F1, F2 measured in saliva and sputum. DeNora et al discloses that concentrations are inversely correlated to the time it takes blood to coagulate.

Watanable et al (US 5,516,640) disclose a simple and accurate assay of PIVKA-VII, IX, and X.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
September 2, 2005

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09/02/05